REMARKS

Claims 1-14, 16-20, 25-31, 33, 34, 56, 57, 67, 68, 92, 93, 95, and 115-16 and 118-121 were presented for examination after a final rejection. Certain of those claims had been amended in the last response, which was an After Final Supplemental Amendment, and the Examiner indicated that entry of the amendment would not place the application in condition for allowance. The Advisory Action indicated that the amendment would be entered for purposes of appeal; however, in a subsequent discussion, the Examiner indicated the amendment had not been entered. Accordingly, the claims in this amendment are marked to reflect changes made from the last set of claims that were entered.

Claim 1 is amended in paragraph (c) to require the microdevice of the claim to meet one of two claim limitations: either the device must comprise a magnetic material, or the binding partner must be selected from the group consisting of a cell, a cellular organelle, a virus, and an antibody. The use of a magnetic material is supported throughout the specification, and specifically at, *e.g.*, page 15, lines 20-24. ("For example, microdevices with certain magnetic properties can be used with magnetic force. In a specific example, the microdevice can comprise one or more types of magnetic materials, such [sic] ferro- or ferri-magnetic materials in the middle of the substrate.")

The specification describes varies binding partners that may be included in the device, for example at page 22, lines 25-31, and page 45, lines 5-7. Those specifically named include a cell, a cellular organelle, a virus, and an antibody. Thus this alternative embodiment of the claimed invention in amended claim 1 is also supported by the specification as filed.

Claim 1 was also amended to include a size limitation that is taken from the specification at page 20, line 15, and the other claims having size limitations (6, 56, 67) were amended to correspond to this limitation in claim 1.

Claims 56 and 67 have been amended similarly to claim 1, to require the microdevice to comprise a magnetic material, or to comprise a binding partner that is a cell, cellular organelle, virus

or antibody. Claim 26 was also amended in view of the amendment to claim 1. Claims 13, 14 and 16 were amended to correct minor typographical or grammatical irregularities.

In addition, new claims 120 and 121 have been added, separately claiming each of the two alternatives that are recited in paragraph c) of amended claim 1. The amendments add no new matter, and place the claims in condition for allowance as explained below. Entry of the amendment and reconsideration in light of the following comments are respectfully requested.

Clarity of the Claims

In the latest Advisory Action, the Examiner indicated that the proposed alternative 'or' language of the added claim limitation in claim 1 "does not clearly set forth the purported claim limitation...In light of the recited language, the instant microdevice invention can be interpreted as 'wherein said microdevice comprises said binding partner comprises [sic] a cell, a cellular organelle, a virus, or an antibody' alone without 'magnetic materials.' Thus the teachings from Kaye et al. would still read on the instant invention."

The alleged 'lack of clarity' is understood to mean that the language of claim 1 allows the microdevice to satisfy either one of the two recited alternative limitations, but does not require the device to satisfy both requirements—that appears to be the real issue the Examiner is raising. The applicant agrees that the 'or' language of claim 1 permits the claim to cover a microdevice that comprises either a magnetic material or a binding partner selected from those recited—a device having both of those features would also, of course, satisfy this limitation. However, the applicant asserts that Kaye does not teach a microdevice that meets either of these limitations, and the claims are therefore allowable over that reference.

Rejection for Anticipation by Kaye under 35 U.S.C. 102

The applicant previously demonstrated that Kaye does not disclose a microdevice that comprises a binding partner. In the Advisory Action, the Examiner noted that "Kaye et al. teach application for the device in many aspects, including biological assays, biological systems and

biological [sic] of interest including [sic: high] throughput screens (See page 19, lines 2-8). Particularly, Kaye et al. also give some, not limited, examples such as enzymes, receptors, signaling systems, receptor genes. Supra. It is noted that applicant recites the binding partner "that is capable of binding to a moiety to be manipulated," and the binding partner comprises "a cell, cellular organelle, a virus or an antibody." The examples given by Kaye et al. include receptor which is also a cellular organelle on cell surface. Taken together, the instant invention would still be rendered anticipated under Kaye et al. reference."

To discuss this anticipation rejection, it is critical to recognize what Kaye (GB 2,306,484A) is about: Kaye describes a particle upon which a compound or a library of compounds could be built. (Abstract.) Kaye does *not* appear to disclose a particle with such a compound or library attached to it, only the concept of building a combinatorial library that "may comprise any convenient number of individual members...of suitable compounds, for example peptides, peptoids and other oligomeric compounds (cyclic or linear), and template-based molecules, for example benzodiazepindes, hydantoins, biaryls, polycyclic compounds... The numbers quoted and the types of compounds listed are illustrative but not limiting." (Page 18, lines 14-21.) Kaye does not, however, describe an embodiment of its particle that has a compound or library attached to it: at most, this passage from Kaye offers an invitation to experiment with making libraries using its microparticle. That is not sufficient disclosure to establish either an obviousness rejection or an anticipation rejection.

Kaye then discloses that a library of compounds *can* be screened for its interaction with other moieties ("Combinatorial Libraries are intended for testing in a variety of assays. The purpose of any assay is to test the ability of library elements or compounds to modulate activity in a test system of interest. Particularly preferred, but in no way limiting, are biological assays, biological systems and biologicals of interest including high throughput screens. Convenient biologicals of interest include proteins such as enzymes, receptors, signaling systems, reporter genes, and the like." (Page 19, lines 1-8).)

Again, it is important to note what Kaye actually says: it does not suggest a particle bound to any 'biologicals': instead, it suggests making and testing a library of undisclosed compounds. Testing of such libraries does not necessarily occur while the compound or library is attached to a particle: frequently, when a library is built on a solid support, the library of such compounds is cleaved from the support prior to testing, and Kaye is silent on this point, so it does not disclose testing the library on its particles. And *testing* of a library, as is well known in the art, does NOT necessarily result in binding to a target of interest. Indeed, Kaye does not refer to 'binding' to a target, only to modulating an activity of a target. Therefore, Kaye does not disclose a particle comprising a binding partner.

Furthermore, Kaye does not disclose or suggest a particle that would comprise a binding partner, even if the particle were used to make a library, and the library were tested while still attached to the particle. Kaye's suggestion to make and use a library of compounds simply does not disclose a particle that would necessarily have a binding partner attached to it inherently, as would be required to support a rejection based on inherency. (See MPEP 2112 (IV): ""In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).")

Claim 1 requires a microdevice comprising a binding partner. Nothing in Kaye was shown to disclose a device comprising, either expressly or inherently, a binding partner. Therefore, Kaye does not anticipate claim 1, and this rejection should be withdrawn.

Obviousness

First, as the Examiner indicated in the Advisory Action, no obviousness rejection based on Kaye has ever been presented. However, during an interview with the Examiner prior to the Supplemental Amendment, the applicant was asked to address potential obviousness arguments.

The applicant therefore offered arguments to counter a conclusion of inherency, without prejudice to the applicant's right to rebut any obviousness case that the Examiner may propose.

As shown above, Kaye does not disclose a particle comprising a binding partner. Moreover, Kaye does not suggest any reason to attach a binding partner to its particle: Kaye relates to making compounds or libraries of compounds, which could be tested against a biological target. The testing may or may not occur when the library is attached to the particle, and the testing may or may not result in modulation of a biological activity or binding to a biological. This does not provide motivation to attach a binding partner to the microparticle in Kaye, only to make compounds that can be tested for an ability to modulate activity of a target.

Also, getting from the particle that Kaye discloses to a particle comprising a binding partner requires invention: the user must design and construct a compound or library with no guidance from Kaye. The binding partner must be "capable of binding to a moiety to be manipulated"; Kaye neither discloses nor suggests the desirability of manipulating a moiety or of selecting a suitable binding moiety for manipulation of a moiety. Instead, Kaye relates to making compounds that can be tested for their ability to modulate activities of targets, not to bind a target to the particle, or to manipulate a moiety. For an obviousness analysis, the invention must be viewed as a whole: Kaye does not disclose or suggest the invention as a whole, a coded particle with an attached binding partner, where the binding partner is in turn capable of binding to a moiety to be manipulated.

Next, in the interest of compact prosecution, the applicant will briefly discuss obviousness under the disputed assumption that Kaye renders obvious a microdevice comprising a binding partner.

Even if Kaye rendered obvious a microdevice comprising a binding partner, the amended claim 1 imposes a further limitation: as stated above, the microdevice must either "comprise[s] a magnetic material" or the binding partner of the microdevice must "comprise[s] a cell, a cellular organelle, a virus, or an antibody."

Kaye does not render obvious a device that "comprises a magnetic material"

Kaye does not appear to disclose any microparticle having a magnetic material. This was pointed out before, and the Examiner said, "The same microdevice would be subject to further separation subsequent to synthesis. Using magnetic materials for separation is well-known and widely practiced in the art. It may need further determination with respect to the issue of obviousness under 35 USC 103(a), albeit this has not been brought up in the previous Office Action."

First, modification of Kaye to allow means for magnetic separation is not rendered obvious by the general observation that magnetic separation is known in the art, so if that is to be the basis for an obviousness rejection, it should be supported by evidence that one of ordinary skill would have been motivated to apply magnetic separation to the Kaye particles. Kaye discloses a clear preference for construction materials that are "chemically inert" (page 7, line13) to the "rigours of library synthesis" (page 8, last line), since the purpose of the Kaye device is to serve as a surface for chemical transformations. Kaye describes a variety of polymeric materials as well as silicon and glass for its particles; it mentions that the coded feature can be "silicon, silicon dioxide or a metal...Such materials offer the additional advantage of comparative robustness, and, in certain cases, chemical inertness." (Page 11, lines11-15). But Kaye goes on to say that the particles "may be manufactured from metals such as aluminum or gold, as well as polyamide or other polymeric or resin materials. Preferred materials for the manufacture of subparticles are silicon and silicon dioxide." (Page 11, lines 18-21). Thus Kaye provides a clear preference for non-metals, and a clear bias against reactive metals if a metal is used: the examples, the bias expressed by Kaye against 'non-inert' metals for construction of its particles, and the purpose of those particles would all have led a person of ordinary skill to avoid common magnetic materials when making particles for the purpose Kaye's particles are designed. Thus modification of Kaye to incorporate a magnetic material is counter to the express teachings of Kaye, and would not have been an appealing choice to the person of ordinary skill.

However, regardless of any modification of Kaye to adapt its particles for magnetic separation, the claims require a microdevice that comprises "a binding partner capable of binding to a moiety to be manipulated". Kaye's microparticles do not comprise a binding partner *or* a

magnetic material, and as is shown below, Kaye does not even suggest the desirability of modifying its particle to comprise a binding partner, or using it to manipulate a moiety. Thus the teachings in Kaye are inadequate to support an obviousness rejection.

Kaye does not render obvious a binding partner that "comprises a cell, a cellular organelle, a virus, or an antibody"

Moreover, Kaye does not even suggest the *desirability* of attaching a binding partner such as those enumerated in claim 1 (a cell, a cellular organelle, a virus, or an antibody) to the particle: it discloses that an unspecified compound library could be made using the particle, and that the unspecified compound library could then be tested for its ability to modulate the activity of a biological. ("The purpose of any assay is to test the ability of library elements or compounds to modulate activity in a test system of interest.") Kaye thus does not suggest any reason to attach a binding partner to its particles, it merely invites their use for synthesizing libraries, then indicates that such libraries (*not* 'particles') are useful for testing in search of compounds that modulate biological activities (*not* 'bind a biomolecule to a particle').

More particularly, Kaye does not render obvious the microdevice of claim 1 that comprises any of the enumerated binding partners ("a cell, a cellular organelle, a virus, or an antibody"). The Examiner, in the Advisory Action, indicated that Kaye listed "receptor which is also a cellular organelle on cell surface." Equating 'receptor' with 'cellular organelle' is considered inconsistent with the normal usage of those terms. No support for that statement was offered, and should the Examiner rely upon that assertion for a rejection, the applicant requests evidence that it is not repugnant to the ordinary meaning of those terms.

Thus, as shown here, Kaye does not render obvious the microdevice of claim 1 having a binding partner; and it even more clearly fails to render obvious the further limitations requiring that either the microdevice must comprise a magnetic material, or the binding partner must comprise a cell, cellular organelle, virus or antibody. Accordingly, Kaye does not render claim 1 obvious.

Additionally, the dependent claims include further limitations that are neither anticipated nor obvious in view of Kaye. For example:

Claim 14 requires a metal layer comprising nickel or a CoTaZr alloy; neither of these is disclosed or suggested by Kaye.

Claim 27 requires a plurality of binding partners, each of which binds to a different moiety, which is inconsistent with Kaye's disclosure, in which each particle would have a single compound attached according to the library synthesis methods summarized.

Claim 34 requires a dye, radioactive substance or fluorescent substance, none of which is disclosed or suggested by Kaye.

Claim 56 recites a kit including microdevices and a chip for manipulating them, which is not disclosed or suggested by Kaye. Claim 67 recites "an array for detecting moieties", which is clearly not suggested or disclosed by Kaye.

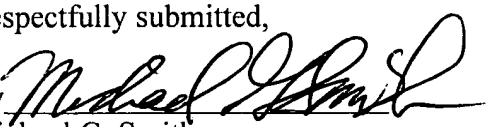
Finally, new claims 120 and 121 separate the two alternatives introduced into claim 1, since they separately require a microdevice that comprises one of those two features. Accordingly, these claims are allowable over Kaye unless the Examiner can demonstrate that Kaye discloses or suggests each of those features.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 471842000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 5, 2006

Respectfully submitted,

By 

Michael G. Smith
Registration No.: 44,422
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
(858) 720-5113